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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,445	09/30/2003	Osamu Seshimoto	JG-TT-4854C-2	4129
7590	11/08/2004		EXAMINER	
Jules E. Goldberg, Esq. REED SMITH LLP 599 Lexington Avenue New York, NY 10022			SORKIN, DAVID L	
		ART UNIT	PAPER NUMBER	1723

DATE MAILED: 11/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/674,445	SESHIMOTO ET AL. <i>TH</i>	
	<b>Examiner</b>	<b>Art Unit</b>	
	David L. Sorkin	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 August 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 10-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 10-18 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 23 August 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. 09/287,424.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Priority***

1. The instant application, filed 29 September 2003 is not entitled to be a continuation of Application No. 09/642,528 because the applications were never co-pending. In 09/642,528 a notice of appeal was filed 2/28/2003. 37 CFR 1.192(a) requires an appeal brief be filed within a two month extendable time period. A four-month extension of time extended the date to file a brief to 8/28/2003. No brief was filed; therefore, 09/642,528 became abandoned 8/28/2003. The instant application was filed about one month after the abandonment of 09/642,528.
2. Likewise, the instant application was never co-pending with 09/287,424, which was abandoned 8/22/2000.
3. The instant application is not entitled to the benefit of Japanese application 1998-099426, because it was filed more than one year prior to filing the instant application.

### ***Drawings***

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "suction line", "means for continuously placing" and "means for moving the suction port" must be shown or the features canceled from the claims. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

5. The disclosure is objected to due to the ineligible priority claims discussed above.
6. The specification is objected to as failing to comply with 37 CFR 1.75(d)(1).

Regarding the claimed features "means for continuously placing a blood filter unit in a vertical position in a blood collecting tube", "means for moving the suction port of the blood filter into contact with the connector; and such that when a vacuum is applied through the manifold, blood is drawn from the blood collecting tubes into the blood filter and through the glass fiber filter and for moving the suction port of the blood filter out of contact with the connector after a predetermined amount of blood has been filtered from the collecting tubes", and "grasp means for elevating each blood collecting tubes to connect each blood filter unit to the connector", the specification must describe the corresponding structure for each means-plus-function recitation. See MPEP 2181

where it is stated based upon *Wolfensperger* 133 USPQ at 542 and *B. Braun Medical Inc. v Abbot Labs*, 43 USPQ2d at 1896 (Fed. Cir. 1997), "the USPTO may still require the applicant to amend the specification ... to explicitly state, with reference to the terms and phrases of the claims, which structure, materials, or acts perform the function recited in the claim element".

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 10-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. These claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While it is unclear what is being claimed, as discussed below, to the extent understood there is no support for the structural element "means for moving the suction port of the blood filter into contact with the connector; and such that when a vacuum is applied through the manifold, blood is drawn from the blood collecting tubes into the blood filter and through the glass fiber filter and for moving the suction port of the blood filter out of contact with the connector after a predetermined amount of blood has been filtered from the collecting tubes". No structure or structures is associated with such a function in the original specification. Particularly, the examiner is unaware of any association of a structure with "after a

predetermined amount of blood has been filtered", in combination with the other functions of the means-plus-function recitation.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 10-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

11. The scope of the feature "means for continuously placing a blood filter unit in a vertical position in a blood collecting tube", recited in claim 10, is unclear due to lack of association of such a function with corresponding structure in the specification.

"[P]ursuant to this provision [35 U.S.C. 112, sixth paragraph], structure disclosed in the specification is 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim. This duty to link or associate structure to function is the quid pro quo for the convenience of employing 112, paragraph 6" *B. Braun Medical Inc. v Abbot Labs. supra*.

12. The scope of the feature "grasp means for elevating each blood collecting tubes to connect each blood filter unit to the connector", recited in claim 15, is unclear due to lack of association of such a function with corresponding structure in the specification.

13. The scope of the feature "means for moving the suction port of the blood filter into contact with the connector; and such that when a vacuum is applied through the manifold, blood is drawn from the blood collecting tubes into the blood filter and through the glass fiber filter and for moving the suction port of the blood filter out of contact with

the connector after a predetermines amount of blood has been filtered from the collecting tubes", recited in claim 10, is unclear due to lack of association of such a function with corresponding structure in the specification.

***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claim 10-18 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 11-295301. JP 11-295301 is the publication of the instant application's priority document, to which applicant is not eligible for priority as explained above. JP 11-295301 was published 29 October 1999, more than one year before the filing of the instant application.

***Response to Arguments***

16. Applicant's arguments have been considered but are moot in view of the new grounds of rejection.

***Conclusion***

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 571-272-1148. The examiner can normally be reached on 9:00 -5:30 Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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David L. Sorkin  
Primary Examiner  
Art Unit 1723

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